

Appendix A

Detailed DSM Plan Checklist

Was item included in the DSM plan?	Included?	
	Yes	No
Brief description of the protocol		
Primary and secondary outcome measures		
Inclusion/exclusion criteria		
Sample size		
List of participating enrolling clinics or data collection centers		
Projected timetable		
Target population distribution (e.g., women, minorities, etc)		
Data acquisition and transmission		
Data entry methods		
Data analysis plan		
Quality assurance plan		
Reporting mechanisms of AEs/SAEs to the IRB, FDA, and NIDA.		
Reporting mechanisms of IRB actions to NIDA		
Report of changes or amendments to the protocol		
Trial stopping rules		
Conflict of interest		
Potential risks and benefits for participants		
Collection and reporting of AEs and SAEs		
Management of SAEs or other study risks		
Plans for Interim Analysis of efficacy data		
Responsibility for data and safety monitoring		
Frequency of DSM reviews		
Content of DSM report		
DSM Board Plan (if applicable)		